R2 Technologies, Inc.
Tarhan Kayihan
Director of QA/RA
2603 Camino Ramon, Suite 200
San Ramon, California 94583

November 10, 2022

Re: K213294
Trade/Device Name: Dermal Cooling System
Regulation Number: 21 CFR 878.4340
Regulation Name: Contact cooling system for aesthetic use
Regulatory Class: Class II
Product Code: QPZ, ILO, GED
Dated: October 12, 2022
Received: October 14, 2022

Dear Tarhan Kayihan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin K. Chen -S

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K213294

Device Name
Dermal Cooling System

Indications for Use *(Describe)*
The Dermal Cooling System is a cryosurgical instrument intended for use in dermatologic procedures for the removal of benign lesions of the skin and for use when cooling is intended for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures.

The Dermal Cooling System is further indicated to minimize pain, inflammation, and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief of injections.

When the Dermal Cooling System is used with the R2 Dermabrasion Tips, the intended use includes general dermabrasion, scar revision, acne scar revision, and tattoo removal.

The Dermal Cooling System is intended to be used by trained healthcare professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**K213294**

**510(k) Summary**

**I. SUBMITTER**

**R2 Technologies, Inc.**
2603 Camino Ramon, Suite 200
Bishop Ranch 3
San Ramon, CA 94583

Contact: Mr. Tarhan Kayihan
Director of QA/RA
R2 Technologies, Inc.
Phone: 925-378-4400
tkayihan@r2technologies.com

Date Prepared: October 12, 2022

**II. DEVICE and ACCESSORY**

| | |
|---|---|
| Device Name: | Dermal Cooling System |
| Device Common Name: | Contact cooling for skin lesion pain relief |
| Accessory Name: | R2 Dermabrasion Tips |
| Accessory Common Name: | Brush, Dermabrasion, Manual |
| Regulatory Class: | II |
| Product Code: | QPZ, GED, ILO |
| Regulation: | 21 CFR 878.4340, 21 CFR 878.4800, 21 CFR 890.5720 |

**III. PREDICATE**

The primary predicate device is the Dermal Cooling System, K203006.
The secondary predicate device is the COOLSKIN device, K083008.

**IV. DEVICE DESCRIPTION**

The Dermal Cooling System is identical to the device cleared in K203006. The Dermal Cooling System is a cryosurgical device used to cool the skin, without the use of cryogenic gases or liquids, for the removal of benign skin lesions and for use when cooling is intended for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures. The Dermal Cooling System is further indicated to minimize pain, inflammation, and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief of injections. Surface contact cooling is achieved using a thermoelectric cooler (TEC), with an integrated aluminum plate, to lower the temperature of the skin. For dermabrasion, the Dermal Cooling System handpiece is intended to serve as a handle to facilitate manual movement of the R2 Dermabrasion Tips.

The R2 Dermabrasion Tips are optional accessories for the Dermal Cooling System that may be attached to the distal end of the handpiece to facilitate manual dermabrasion. The R2 Dermabrasion Tips may be used with a commercially available topical or water to facilitate movement of the handpiece across the treatment area.

**V. INDICATIONS FOR USE**

The Dermal Cooling System is a cryosurgical instrument intended for use in dermatologic procedures for the removal of benign lesions of the skin and for use when cooling is intended for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures.

The Dermal Cooling System is further indicated to minimize pain, inflammation, and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief of injections.

When the Dermal Cooling System is used with the R2 Dermabrasion Tips, the intended use includes general dermabrasion, scar revision, acne scar revision, and tattoo removal.

The Dermal Cooling System is intended to be used by trained healthcare professionals.

**VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE**

The Dermal Cooling System ("subject device") and the predicate devices are Class II, thermoelectric contact cooling devices used to cool tissue during dermatologic procedures.

The primary predicate, the Dermal Cooling System, has not been modified for the proposed expanded indication, i.e., minimize pain, inflammation, and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief of injections.

The secondary predicate, the COOLSKIN device, is included to substantiate the proposed expanded indications for use as the cleared indication for the COOLSKIN device (K083008) includes "minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief of injections." The Dermal Cooling System and the COOLSKIN device have these same fundamental scientific technological elements:

- comprised of a cooling unit (chiller) with a cold plate/probe applicator used to cool the skin in the area intended for treatment
- same cooling mechanism - thermoelectric cooling
- controlled contact surface cooling at a targeted treatment site on the skin
- metal cooling interface within an applicator

The key differences that exist between the Dermal Cooling System and the COOLSKIN device are:

- size and shape of cold plate/probe applicator

The differences do not raise new questions of safety and effectiveness with respect to the proposed expanded indication.

**VII. PERFORMANCE DATA**

Performance data is provided in support of the substantial equivalence determination, as summarized in the table below.

Bench testing was completed to demonstrate the ability of the Dermal Cooling System to meet performance specifications.

| Test | Test Method/Requirement | Acceptance Criteria | Results |
|---|---|---|---|
| System Verification | System Performance Test: System performance at lowest expected clinical treatment temperature, at maximum treatment time | System is able to hold the internal coldplate temperature to -16.0°C ± 0.5°C for 20 minutes | Passed |

No other performance testing was performed for the subject device for this Traditional 510(k) since there was no change to the device design or methods for use required for the proposed expanded indication and the range of treatment parameters previously cleared for the Dermal Cooling System (K203006) allows the same cooling characteristics at the skin surface as the secondary predicate, COOLSKIN device.

No preclinical or clinical testing was performed.

**VIII. CONCLUSIONS**

The Dermal Cooling System that is the subject of this Traditional 510(k) is substantially equivalent to both the primary predicate (Dermal Cooling System) and the secondary predicate (COOLSKIN device). The subject device and both predicates are Class II devices intended for use to cool tissue in dermatologic procedures of the skin. The subject Dermal Cooling System and the primary predicate Dermal Cooling System are the same device; there are no changes required in the device design or the method by which the device is used for this expanded indication. The Dermal Cooling System can deliver the same treatment parameters using the same cooling mechanism (i.e., TECs) as the secondary predicate COOLSKIN device. The minor technological differences between the subject device and the secondary predicate are the size and shape of the cold plate/probe applicator; however, these differences do not raise new questions of safety and effectiveness for the proposed expanded indication.